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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,532	12/30/2003	Mineo Yamakawa	21058/0206764-US0	8878

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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01/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/749,532

Applicant(s)

YAMAKAWA ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/30/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2, 4-7, 10-12, 15-19 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-7, 10-12, 15-19 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2007 has been entered.

Status of Claims

Claims 1-2, 4-7, 10-12, 15-19 and 37-39 are pending and under examination.

Withdrawn Rejection

In view of the amendments to the claims the following rejections in the last Office action have been withdrawn: 35 USC 112, first paragraph rejection (new matter) and second paragraph in-part.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-7, 10-12, 15-19 and 37-39, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Written Description Rejection

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107

F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The specification fails to provide an adequate written description for a method for identifying a peptide that binds to a surface having a target geometrical shape. The disclosure fails to disclose any peptide that has been identified from a phage display library that binds to a target geometrical shape. The description in the disclosure for each of the huge components of the methods is provided only in terms of definition. It does not describe the kind and/or shape assumed

by the surface to contain any kind of target. A listing or definition of every possible surface or target does not constitute a written description of every species in a genus. It would not "reasonably lead" those skilled in the art to any particular species. In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). The disclosure is replete with generalities, the exemplification even for a single species is nil. To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the genus of the invention. Applicants are further referred to the CAFC decision in the University of California vs. Eli Lilly and Co. CAFC 43 USPQ2d 1398 7/22/1997 with respect to adequate disclosure of the scope of the presently claimed method. Adequate disclosure, like enablement, requires representative examples, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. See In re Riat (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr. (CCPA 1971) 444 F 2d 349, 151 USPQ 724

(for enablement) and University of California v. Eli Lilly and Co. (for disclosure).

Response to Arguments

Applicants argue that the claims have been amended to obviate this rejection. However, even with the amendments to the claims, this rejection has not been overcome.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-7, 10-12, 15-19 and 37-39, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is maintained only for the claims as reiterated immediately below.

B). The term "specific" in claim 1 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in

the art would not be reasonably apprised of the scope of the invention. It is not clear as to the basis by which a specific geometrical pattern of a material is based given no structure or name for said material of a target surface. It is not clear as to the qualifying features of said target surface material to the target.

Since applicants have not responded to this rejection, it is believed that applicants are acquiescing therewith.

The newly amended claims are rejected as follows:

1. Claim 1 is not clear whether the peptide binds to the flat surface or to a target on the flat surface
2. Claim 2 does not further claim 1 as the limitations recited in claim 2 is already in the base claim 1.
3. Claim 15 is inconsistent with claim 1. Claim 1 recites only a flat surface. Thus, a "smooth or curved" lacks antecedent support from the base claim.
4. Claim 19 does not further limit claim 1 since the limitations recited in claim 19 is already recited in claim 1.
4. Non-sequitur in claim 39 of "the one or more desired elements." The present amended claim 1 cancelled this phrase.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-2, 4-7, 10, 16, 18, and 19, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Naik et al (Nature).

Naik discloses at page 169, cols. 1 and 2 a method of identifying a silver binding peptides from a combinatorial phage display peptide library comprising contacting a phage display peptide library with a inorganic surface, as silver. Naik discloses at page 170 up to page 171 that the silver particles were analyzed by transmission electron microscope. The examination of the silver nanoparticles obtained using AG4 peptide revealed the presence of hexagonal, spherical and triangular silver particles. The silver crystal exhibited a flat plate-like morphology. See further the Methods at page 172 which provide a detail description of the method. The broad claimed method utilizing broad components is fully met by the process of Naik using specific components therein.

Claims 1, 4-7, 10-12, 15 and 18-19, as amended, are rejected under 35 U.S.C. 102(e) as being anticipated by Belcher (US 20030113714).

Belcher discloses in the abstract a method for selective binding of amino acid oligomers to semiconductor and elemental carbon-containing materials. Belcher discloses at [0047] that "elemental carbon-containing molecule" generally refers to allotropic forms of carbon. Examples include, but are not limited to, diamond, graphite and highly ordered pyrolytic graphite (HOPG). At paragraph [0048] the "substrate" may be a microfabricated solid surface to which molecules attach through either covalent or non-covalent bonds and includes, e.g., silicon, mica, gold, silver, metal, metal alloy and combinations thereof capable of having functional groups such as amino, carboxyl, thiol or hydroxyl incorporated on its surface. The substrate may be porous, planar or nonplanar. The substrate includes a contacting surface that may be the substrate itself or a second layer (e.g., substrate or biologic material with a contacting surface) made of organic or inorganic molecules and to which organic or inorganic molecules may contact. Belcher discloses that previously it was shown that peptides may bind to semiconductor material. Semiconductor materials useful in binding

peptides include, but are not limited to gallium arsenide, indium phosphate, gallium nitrate, zinc sulfide, aluminum arsenide, aluminum gallium arsenide, cadmium sulfide, cadmium selenide, zinc selenide, lead sulfide, boron nitride and silicon. At paragraph [0054] it was disclosed that the method provides a random organic polymer pool using a Phage-display library. A Phage-display library is a combinatorial library of random peptides containing between 7 and 12 amino acids fused to the pIII coat protein of M13 coliphage, providing different peptides that are reactive with crystalline semiconductor structures or other materials. At paragraph [0055] peptide sequences have been developed with affinities for various materials such as semiconductors, and elemental carbon-containing molecules such as graphite. At paragraph [0056] Belcher discloses that using a Phage-display library, protein sequences that successfully bound to the specific crystal were eluted from the surface, amplified by, e.g., a million-fold, and reacted against the substrate under more stringent conditions. This procedure was repeated between **three and seven times to select the phage in the library with the most specific binding peptides. After, e.g., the third, fourth and fifth rounds of phage selection, crystal-specific phage were isolated and their DNA sequenced, identifying the peptide binding**

that is selective for the crystal composition (for example, binding to GaAs but not to Si) and crystalline face (for example, binding to (100) GaAs, but not to (111)B GaAs).

Response to Arguments

Applicants state that independent claim 1 has been amended to include the limitations "synthesizing the identified peptide" and "confirming the identified peptide's binding specificity." Support for these amendments can be found in paragraph [0036] of the specification. Neither Naik et al. nor Belcher et al. disclose these two features. Therefore, neither Nail et al. nor Belcher et al. anticipate claim 1 or any of the claims that depend from claim 1.

In response, attention is drawn to Belcher which discloses at **e.g.**, paragraph:

[0059] Phage, tagged with streptavidin-labeled 20-nm colloidal gold particles bound to the phage through a biotinylated antibody to the M13 coat protein, was used for quantitative assessment of specific binding. X-ray photoelectron spectroscopy (XPS) elemental composition determination was performed, monitoring the phage substrate interaction through the intensity of the gold 4f-electron signal (FIGS. 2a-c). Without the presence of the G1-3 phage, XPS confirmed that the antibody and the gold streptavidin did not bind to the GaAs(100) substrate. The gold-streptavidin binding was, therefore, specific to the peptide expressed on the phage and an indicator of the phage binding to the substrate. Using XPS it was also found that the G1-3 sequence isolated from GaAs(100) bound specifically to GaAs(100) but not to Si(100)

(see FIG. 2a). In a complementary fashion the S1 clone, screened against the (100) Si surface, showed poor binding to the (100) GaAs surface. [0059] Phage, tagged with streptavidin-labeled 20-nm colloidal gold particles bound to the phage through a biotinylated antibody to the M13 coat protein, was used for quantitative assessment of specific binding. X-ray photoelectron spectroscopy (XPS) elemental composition determination was performed, monitoring the phage substrate interaction through the intensity of the gold 4f-electron signal (FIGS. 2a-c). Without the presence of the G1-3 phage, XPS confirmed that the antibody and the gold streptavidin did not bind to the GaAs(100) substrate. The gold-streptavidin binding was, therefore, specific to the peptide expressed on the phage and an indicator of the phage binding to the substrate. Using XPS it was also found that the G1-3 sequence isolated from GaAs(100) bound specifically to GaAs(100) but not to Si(100) (see FIG. 2a). In a complementary fashion the S1 clone, screened against the (100) Si surface, showed poor binding to the (100) GaAs surface.

Attention is drawn to Naik which discloses at e.g., page 169, col. 2:

The phages expressing peptides that exhibited selective affinity for silver. after several rounds of panning, were eluted from the surface of the silver particles and re-amplified. DNA from the phages was isolated and sequenced to obtain the genetic information encoding for the displayed peptides. Analysis of over 30 independent clones provided only three different peptide sequences: AG3, AG4 and AG5 (table I) of these three" peptides, AG4 was the predominant sequence present within the sequenced clones. The silver-binding peptides do indicate a preferential enrichment of proline and hydroxyl-containing amino acid residues, and there appears to be positional conservation of some of the amino acid residues. **We confirmed the binding of the phage clones to silver surfaces using indirect immunofluorescence (Supplementary Information Fig. S1).** (Emphasis added.)

Claims 1, 4-7, 18 and 19, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (Science).

Lee discloses at page 893, Fig. 1 a method of identifying peptide by contacting a phage library with a surface comprising a target with a geometrical shape. See the entire article.

Since applicants have not responded to this rejection hence, it is believed that applicants are acquiescing therewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-2, 4-7, 10-12, 1516, 18-19 and 37-39, as amended and added, are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Naik or Belcher or Lee in view of Puentes (Science).

Each of Naik, Belcher and Lee is discussed above. Each of these references does not disclose a surface comprising a surfactant. However Puentes teaches at page 2115 up to page 2117 the use of surfactant. Puentes teaches that the use of surfactant results in the preparation of wide range of shapes including rod, teardrops, and tetrapods and branched tetrapods. The shapes can be made simply by varying surfactant compositions

as learned from the prototypical CdSe system. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a surfactant in the surface of e.g., Naik as taught by Puentes. The advantages taught by Puentes in the use of surfactant composition would provide the motivation to one having ordinary skill in the art at the time the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Naik or Belcher or Lee as applied to claims 1-2, 4-7, 10-12, 15-19 and 37-39 above, and further in view of Freeman et al (Science).

Naik or Belcher or Lee does not disclose a surface with a Teflon as recited in claim 17. However, Freeman at page 1629 teaches a substrate comprising Teflon. Freeman discloses that the Teflon is conventionally used as a substrate. The solution-based process taught by Freeman is extremely general encompassing numerous permutations of insulating and conducting substrates including Teflon. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as a surface substrate, Teflon in the method of e.g., Naik as taught by Freeman. The different permutations that can be done to the conventional substrate as

Teflon as taught by Freeman would provide the motivation to one having ordinary skill in the art, at the time the invention was made.

Response to Arguments

Applicants state that amended independent claim 1 includes the limitations of "synthesizing the identified peptide" and "confirming the identified peptide's binding specificity." These limitations are neither taught nor suggested by any of the applied references or any combination of the applied references. Therefore, no combination of the applied references renders claim or any of the claims that depend on claim 1 obvious.

In reply, the response above is incorporated herein since applicants merely reiterated their response from above.

No claim is allowed.

Conclusion

This is a continued examination of applicant's earlier Application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

Application/Control
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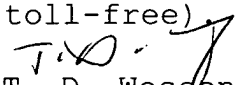
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expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 17, 2007